



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,878	12/09/2003	Ruchika Singhal	1023-334US01	4796

28863 7590 01/03/2006  
SHUMAKER & SIEFFERT, P. A.  
8425 SEASONS PARKWAY  
SUITE 105  
ST. PAUL, MN 55125

EXAMINER
----------

GREENE, DANA D

ART UNIT	PAPER NUMBER
----------	--------------

3762

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/730,878		SINGHAL ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Dana D. Greene		3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/29/05</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, 10, 13, and 14 stand rejected under 35 U.S.C. §102(b) as being anticipated by Kirkpatrick et al. (US 6,480,743 B1, hereinafter "Kirkpatrick"). With reference to claims 1 and 14, Kirkpatrick is considered to disclose:

at least two interconnected modules, each of the modules comprising a respective one of at least two housings (see col. 6, ln. 20-28, col. 14, ln. 22-30, and fig. 4, Kirkpatrick). The disclosed power supply and central processing unit are considered to anticipate the claimed interconnected modules because both modules perform assigned functions within the implantable medical device (neurostimulator);

an overmold that at least partially encapsulates each of the housings, the overmold comprising a lead connection module configured to accept an external lead (see col. 8, ln. 47-55, col. 9, ln. 7-12, and fig. 2, Kirkpatrick). The disclosed lead connector 220 is considered to anticipate the claimed lead connection module because both are configured to receive one or more electrical leads. In this connection, the lead connection module of Kirkpatrick and the claimed connection module both function within an encapsulation formed of biocompatible materials.

With reference to claim 2, Kirkpatrick is considered to disclose:

an implantable medical device, wherein at least one module comprises a control module containing electronic components (see col. 13, ln. 43-54, Kirkpatrick). The disclosed CPU is considered to anticipate the claimed control module because both include electronic components associated with the functions of the implantable medical device or neurostimulator.

Referring to claims 3-4 and 13, Kirkpatrick is considered to disclose:

an implantable medical device wherein the overmold comprises a first material and a second material, and the lead connection module is deployed within the first material and wherein the first material comprises a non-elastomeric material (see col. 8, ln. 47-55 and col. 9, ln. 8-15, Kirkpatrick). Kirkpatrick anticipates the claimed device having specific materials and a lead connection module because both include a lead connector module adapted to receive one or more electrical leads, which facilitate electrical connection in a substantially fluid-tight environment with biocompatible materials.

With reference to claim 5, Kirkpatrick is considered to disclose:

an implantable medical device, the lead connection module comprising at least one feed-through wire to electrically couple an external lead to an electronic component within the implantable medical device (see col. 8, ln. 47-55, Kirkpatrick). The disclosed lead connector is considered to anticipate the claimed lead connection module because both facilitate electrical connection to a conductor in the lead coupling an electrode to circuitry within the IMD/neurostimulator.

Referring to claims 6-7, Kirkpatrick is considered to disclose:

an implantable medical device, wherein the lead connection module includes a mechanical lead securing mechanism comprising a tool-less mechanical lead securing mechanism (see col. 8, ln. 47-55, Kirkpatrick). The disclosed connector mechanism is considered to anticipate the claimed mechanical lead securing mechanism because both act to physically secure the lead to the IMD and facilitate an electrical connection.

With reference to claims 9-11, Kirkpatrick is considered to disclose:

a first material configured to hold at least part of the housing of one of the modules; a second material coupled to the first material; and a lead connection module configured to accept an external lead, the lead connection module being deployed within the overmold (see col. 8, ln. 47-55 and col. 9, ln. 7-15, Kirkpatrick). The disclosed material is considered to anticipate the first and second material because they are all biocompatible and capable of securing the modules. In this connection, the lead connector of both Kirkpatrick and the claimed invention act to physically secure the lead to the device and facilitate electrical connection in a substantially fluid-tight environment with biocompatible, non-elastomeric, or elastomeric materials

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Kirkpatrick. Kirkpatrick discloses the claimed invention except for an implantable

medical device with a maximum thickness of between approximately 4 millimeters and approximately 8 millimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to produce a neurostimulator with a thickness range between 4 and 8 millimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art (see *In re Aller*, 105 USPQ 233). The implantable medical device of Kirkpatrick has a significantly small size and reduced profile leading to a reduced risk of infection, skin erosion, and cosmetic disfigurement; which is also a benefit of the thickness range of the claimed device.

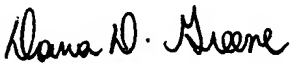
Claims 11 and 12 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kirkpatrick in view of Baudino (6,671,544 B2, hereinafter "Baudino"). Kirkpatrick is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed elastomeric and silicone material. However, Baudino is considered to disclose the claimed material (see col. 3, ln. 40-51, Baudino). It would have been obvious to one of ordinary skill in the art to combine the teachings of Kirkpatrick with the silicone materials of Baudino for the purpose of configuring an overmold capable of changing shape depending upon the arrangement of the modules it encapsulates.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dana D. Greene



George Manue  
Primary Examiner